REMARKS

Please enter the amendments above in view of the following remarks. The remarks are preceded by quotations from the most recent action in small bold type.

> **Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**
>
> **The claims are directed to screening for an agent to reduce wrinkles. The specification teaches in the examples that p21 knockout mice get more wrinkles than average when exposed to UVB. No assay, tested compounds, data regarding p21 for any compound or any compound found by any method that reduces wrinkles is shown in the specification as originally filed.**

The Applicants respectfully traverse. The claims are directed to a method that includes (1) determining whether a test agent increases or induces a component of the p21 signal transduction pathway; and (2) correlating the ability of the test agent to increase expression, activity or levels of a component of the p21 signal transduction pathway with the agent's ability to reduce the appearance or formation of wrinkles.

1. First, the action alleges that there are "no . . tested compounds" nor "data regarding p21 for any compound or any compound found by any method that reduces wrinkles" disclosed in the specification. However, the method of claim 1 is a "screening method" and therefore does not require prior knowledge that a compound would function to both increase or induce a component of the p21 signal transduction pathway and to reduce the appearance or formation of wrinkles. In many (but not all) cases, there would be little need to perform the method of claim 1 if such information were available. Thus, under § 112, making and using the claimed invention does not require foreknowledge of compounds that would have the properties sought.

The specification is enabled whether or not it discloses compounds having the desired properties since generally, any compound can be evaluated using the method. Even so, the specification provides general guidance as to agents, e.g., at page 9, lines 13-19. Furthermore, nucleic acids encoding p21 are also available as examples of agents that increase p21 expression and activity.

To conclude, because the method is a screening method, no tested compounds nor data regarding such compounds need be disclosed. The alleged absence of such information is not a basis for rejection under § 112, first paragraph.

2. The Action further contends that the specification provides no assays. However, many assays were known to those of ordinary skill or are disclosed in the specification.[1] For example, the specification explains at page 9, lines 3-9, that:

> Numerous methods of assessing p21 expression are well know in the art, e.g., Northern analysis, ribonuclease protection assay, reverse transcription-polymerase chain reaction (RT-PCR) or RNA in situ hybridization (see, e.g., Sambrook et al. Molecular Cloning: A Laboratory Manual (3.sup.rd ed. 2001)). The level of p21 may be monitored by, e.g., Western analysis, immunoassay, or in situ hybridization. p21 activity (e.g. altered promoter binding and/or transcription activity) may be determined by, e.g., electrophoretic mobility shift assay, DNA footprinting or reporter gene assay.

Given the availability of the Sambrook Manual and high level of skill in the art, there is no need for the specification to recite the details of known assays for gene expression and protein analysis. In addition, the reference cited by the Examiner -- Weinberg (Crit Rev Oral Biol Med) -- itself cites to numerous references that provide assays for p21. According to MPEP § 2164.01, citing Federal Circuit case law, "A patent need not teach and *preferably omits*, what is well known in the art (emphasis added)." Thus, the high level of skill in the art and the assays mentioned in the specification and generally known, e.g., in the Weinberg reference, indicate that the specification enables performing assays.

Thus, contrary to the Examiner's contention that "No assay, tested compounds, data regarding p21 for any compound or any compound found by any method that reduces wrinkles is shown in the specification as originally filed," the specification is adequately enabled because (1) assays are either disclosed or are well known, (2) examples of test agents are provided (even though not needed), and (3) data for tested compounds are not relevant to the enablement of a screening method. The Applicants submit that the rejection should be withdrawn.

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[1] See, e.g., page 8, lines 5-13, providing guidance for wrinkle assays.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

There are many instances of lack of antecedent basis in the claims, for example in claim 1 line 4, "the p21 signal", in claim 2 line 1, "the effect".

The claims have been amended to moot this rejection.

In claim 1 line 6, "the ability of a test agent" is unclear because compounds have activities, not abilities.

The Applicants respectfully disagree. For example, sugar (a compound) is *able* to dissolve in water. Thus, it is proper to say the *ability* of sugar to dissolve water varies with temperature. Likewise, the reference cited by the Examiner refers to "the ability of p21" at page 459, col. 1, final paragraph. Thus, one of ordinary skill would not have any difficulty in understanding the meaning of "the ability of a test agent."

In claim 6 last line, "it" is unclear as to what may be intended.

Claim 6 has been amended.

In claim 11 "UVB induced wrinkles" is queried as to how one would know if a wrinkle were or were not UVB induced.

Claim 11 has been cancelled without prejudice.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The title has been amended to "SCREENING FOR SKIN WRINKLING MODULATORS."

Enclosed is Petition for Extension of Time fee. Please apply the fee and any other charges required to maintain the pendency of this application to deposit account 06-1050.

Respectfully submitted,

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/RKTabtiang/
Ramon K. Tabtiang
Reg. No. 55,658

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

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